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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/063,937

05/28/2002

Brent C. Gerberding

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2387

490

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05/16/2006

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

DATE MAILED: 05/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	10/063,937	GERBERDING, BRENT C.	
	Examiner	Art Unit	
	Elizabeth Houston	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-10,13-18,22-28,34 and 35 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 and 22-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-10, 13-15, 26-28, 34, 35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/24/06 has been entered.

Election/Restrictions

2. Newly submitted claim 16-18 and 22-25 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: claim 16 recites "*at least one strut being a connecting strut ... the at least one connecting strut having an region with an enlarged width with a greater radiopacity ... the region disposed between two of the plurality of serpentine bands*" which is directed toward figure 1F. This embodiment was not depicted in the originally filed claims.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 16-18 and 22-25 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

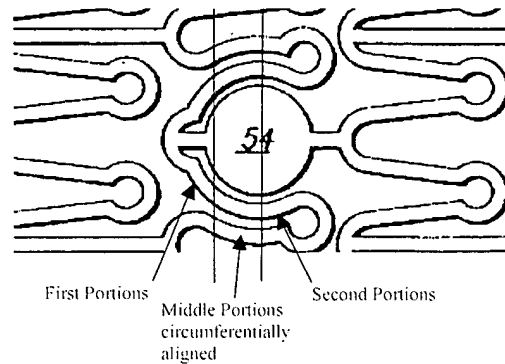
3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Erbel.

5. Cox discloses the stent

6. As to claim 1, in one embodiment, Cox clearly teaches a stent having a longitudinal axis, comprising a plurality of serpentine bands formed of interconnected struts (Figs. 6) including: special struts (54), which extend between peaks and troughs (see below) having a first side with a first region of first curvature relative to the longitudinal axis and a second side with a second region of second curvature relative to the longitudinal axis, the first region opposite the second region and having a radiopaque marker (Col. 3, line 14) between the two regions. Each special strut has a plurality of interconnected struts adjacent the first side and a plurality of interconnected struts adjacent the second side, each having curved regions that curve about marker. Each curved region has a first end and a second end with a middle portion disposed substantially midway between. The middle portions are aligned with one another in a circumferential direction.



7. The special struts are located between the ends of the stent. Some of the special struts (54b or 54c) are located anywhere between the middle of the stent and halfway from the middle to the end of the stent. In other embodiments disclosed by Cox (Figs. 11-15), there is a plurality of radiopaque markers and special struts at the end of the stent. Regarding claims 26 and 27 requiring that the special struts ~~that are~~^{be} located only in the intermediate serpentine bands or not at the end of the stent, Cox discloses that the number and location of high-mass links can be varied as the application requires (Col 4, lines 5-14). Additionally, the instant disclosure describes this parameter as merely preferable (see specification Para 0011, Para 0018, Para 0033, Para 0047 and Para 0061) and does not describe it as contributing any unexpected result to the stent. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

8. Cox does not disclose a stent with a cover.

9. Erbel discloses an endovascular prosthesis (Fig. 3) or stent (20) comprising at least one cover (25) disposed about at least one section of interconnected serpentine segments, marked at the distal end and proximal end by a plurality of radiopaque

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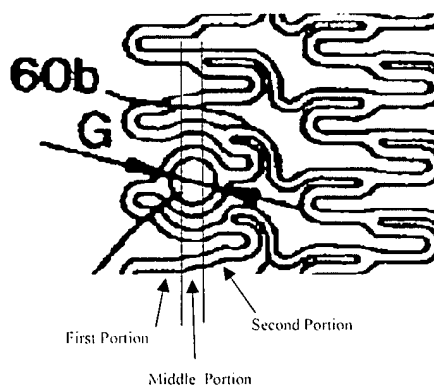
markers (35). Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90). The nonporous section (25) or cover is disposed about the circumference of the stent, but does not extend about an entire circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. The cover extends about the medical device in the region of the special struts. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Paras. 70-72).

10. It would have been obvious to one of ordinary skill in the art to incorporate a cover disposed about the stent in the area of radiopaque markers. Using a cover on the stent enhances the properties of the stent to cause thrombosis at the site of the aneurysm or tear while at the same time allowing blood to flow through the stent and the vasculature. Using radiopaque markers at the edge of the cover facilitates correct placement of the cover at the site of the aneurysm or tear in the body lumen. Erbel provides the motivation. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

11. Claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky (USPN 6,730,116) in view of Erbel et al. (USPN 2004/0116998).

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12. Wolinsky teaches a stent having a longitudinal axis, comprising a plurality of serpentine bands having peaks and troughs and struts extending between and least one band includes special struts (Fig. 3, 28 and Fig. 8, 62a) with enlarged width with greater radiopacity. There is a plurality of interconnected struts on either side of the special strut having a complementary shape to the special strut. The interconnected struts have curved regions have a first end and a second end with a middle portion disposed midway there between. The middle portions are *substantially* aligned with one another.



The special struts are in a region between the ends (edges) of the stent. One of the special struts is located in a serpentine band at one end and the other special strut is located in a serpentine band at another end of the stent. Wolinsky further teaches, “stents can be used to repair aneurysms” (Col. 1, line 36).

13. Regarding claims 26 and 27 Wolinsky does not disclose that the special struts are located only in the intermediate serpentine bands or not at the end of the stent. The instant disclosure describes this parameter as merely preferable (see specification Para 0011, Para 0018, Para 0033, Para 0047 and Para 0061) and does not describe it as

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contributing any unexpected result to the stent. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

14. Wolinsky fails to teach a stent with a cover.

15. Erbel discloses an endovascular prosthesis (Fig. 3) or stent comprising an annular portion with a porous section (20) and a nonporous section (25). As to claims 34-35, the nonporous section (25) or cover is disposed about the circumference of the stent and does not cover the entirety of the stent as seen in Fig. 3. Erbel teaches that the non-porous section "will cause thrombosis or clotting of bodily fluid" (Para 83) as in treating an aneurysm. Erbel further teaches that the partial non-porous or graft covering is beneficial in that it blocks the tear or lesion or aneurysm, while at the same time allows blood to flow from the proximal to the distal end of the vasculature during implantation of the device. (Para70-72). The cover disposed about the stent in a region including radiopaque markers (35). The radiopaque markers designate the proximal and distal ends of the region of the cover. Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90).

16. It would have been obvious to one of ordinary skill in the art to incorporate a cover onto the stent to enhance the capabilities of the stent. Erbel provides the motivation that using a cover on the stent enhances the properties of the stent as it could then be used to promote thrombosis at the regions of aneurysms and tears while allowing blood flow through the lumen. He further provides the motivation for using

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radiopaque markers at the end regions of the cover. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

17. As to Claim 8, Wolinsky in view of Erbel teaches that using radiopaque markers to designate the proximal and distal ends of the region of the cover facilitates correct placement of the stent. However, Wolinsky in view of Erbel does not disclose the size of the cover and therefore does not disclose that the special struts are located anywhere between the middle of the stent and a position one half of the way from the middle of the stent to an end of the stent.

18. It would have been obvious to one having ordinary skill in the art at the time of the invention to alter the size of the cover depending on size of the vessel, the size of the stent and the size of the lesion that it is treating. And therefore the markers could be located at a position one half of the way from the middle of the stent to an end of the stent.

19. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wolinsky in view of Erbel and Cox in view of Erbel as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

20. Wolinsky in view of Erbel and Cox in view of Erbel teach a stent with a cover marked at the periphery by special radiopaque struts as stated above.

21. Wolinsky in view of Erbel and Cox in view of Erbel do not teach a second cover.

22. Barone teaches a stent with two covers shown in Fig. 7. The figure shows two stent grafts occluding where the vessel is ruptured but keeping the flow of the blood through the ostium of the vessel branch. Barone states that the use of 2 covers is

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desirable to repair blood vessels with lesions wherein the wall of the vessel is not in condition to receive and firmly retain an implanted graft (Col 2, lines 20-25 and Col 1, lines 8-17.

23. At the time of the invention it would have been obvious to one of ordinary skill in the art to combine the second cover of Barone into the stent of Wolinsky in view of Erbel and the stent of Cox in view of Erbel. Barone provides the motivation in that a stent with two covers enhances the function of the stent since it can be used to repair branched vessels with multiple lesions. The inventions are analogous with each other and the instant invention and so the combination is proper.

24. Claims 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Erbel and Wolinsky in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

25. Cox in view of Erbel and Wolinsky in view of Erbel disclose the claimed invention as stated above except for the different forms of radiopaque markings.

26. Admission discloses that the radiopacity by be provided by plating, painting, pressing, swaging or welding or "any other suitable means known in the art" (specification page 8, Para 0045). Additionally, Admission discloses, "One of ordinary skill in the art at the time of the invention would recognize that radiopaque markers in the form of plated, coated, painted, swaged or welded radiopaque material have different characteristics." (Remarks, 04/24/06, page 7, Para 4).

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27. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the radiopacity by the various forms since it was well known in the art.

Response to Arguments

1. Applicant's arguments, filed 04/24/06 have been fully considered but they are not persuasive.

2. Regarding claim 1, Applicant states that the curved portions of Cox are not substantially aligned but are displaced by about 20% of the length of the curved portion. However, the claim limitations require that the middle portions be aligned and as shown in the drawing above, they are.

28. In response to applicant's argument regarding claim 22, that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

29. In response to applicant's argument that there is no suggestion or motivation to alter the size of the cover (re: claim 22), the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so

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found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the knowledge to alter the size of the cover is generally available to one of ordinary skill in the art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Houston whose telephone number is 571-272-7134. The examiner can normally be reached on M-Th 8:30-6:00 Alternate Fridays 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

eh 


ANHTUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
